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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/314,889	05/19/1999	GUO-LIANG YU	1488.0310006	5766

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/07/2002 18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/314,889	Yu et al.
Examiner	**Art Unit**
John Ulm	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 21, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *27-119* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *27-119* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

1) Claims 27 to 119 are pending in the instant application.

2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 May of 2001 has been entered.

5) Claims 57, 62 to 70, 73 to 81 and 94 to 100 remain objected to as reciting an improper Markush Group for those reasons of record.

6) Claims 27 to 119 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of Paper Number 9.

Applicant's reliance on *In re Brana*, 51 F.3d 1560,1566, 34 USPQ2d 1436 ,1441 (Fed. Cir. 1995) is misplaced. That court decision determined that a compound which belonged to a family of compounds known to have anti-tumor activity, which is a common and well established specific and substantial utility for that family of compounds, would be reasonably expected to have anti-tumor activity in light of positive *in vitro* data with respect to that particular compound

since that data has proven to be an indicator of anti-cancer activity by other members of that family. The protein of the instant invention does not belong to a family of compounds with a common well established specific and substantial utility. The utility of those members of the receptor family to which the claimed protein in the instant application belongs lies in the knowledge that they modulate a specific physiological activity in response to a specific ligand. Since the instant specification does not disclose the identity of a native ligand for the claimed protein, a knowledge of the pathway (apoptosis) through which that receptor transduces its signal in response to that ligand is not particularly useful.

Applicant urges that the proteins encoded by the nucleic acids of the instant invention, "by virtue of their ability to induce apoptosis, would be useful, e.g., in the treatment of diseases associated with increased cell survival or insufficient apoptosis". Applicant appears to be under the mistaken belief that the exogenous administration of a death domain containing protein to a cell will induce apoptosis in that cell. It will not. A protein of the instant invention is an integral membrane protein and the exogenous administration of such a protein to a cell would not be expected to have any effect upon that cell. At best, the instant specification describes a method of inducing apoptosis in a cell by introducing a heterologous nucleic acid encoding a death domain containing protein into that cell and then inducing the over expression of the protein encoded thereby. This appears to be a rather Rube Goldbergian means of killing a cell, would could otherwise be killed by the simple administration of excessive salt, alcohol, heat or cold. The

killing of a cell by the introduction of a heterologous nucleic acid into that cell is not a substantial and practical utility simply because it provides not specific and substantial benefit to the public.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby induces apoptosis when overexpressed in a cell is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted and would be no different than granting a patent on the process disputed in *Brenner v. Manson* on the premise that the steroid produced thereby was useful as an analytical standard or as a combustible fuel source.

Applicant has cited the Warzocha et al. publication (BBRC 242:376-379, 1998) as evidence that a nucleic acid of the instant invention is associated in some way with Follicular lymphoma. Applicant, however, has failed to identify that portion of the instant specification which specifically asserts that a protein encoded by a nucleic acid of the instant invention is diagnostic or causally associated with Follicular lymphoma. More importantly, the instant specification does not provide a single piece of evidence or line of reasoning which would support any role for DR3 in Follicular lymphoma. The inclusion of any reference to Follicular lymphoma

in the list of disorders presented in the instant specification does not constitute a specific assertion and only serves as evidence of the completeness of this list of virtually all disorders known to be associated with members of the tumor necrosis receptor family. An invention must be patentable at the time that an application is filed. The Warzocha et al. publication was not available to the public at the time that the instant application was filed. Applicant may not rely upon subsequent discoveries by themselves or others to complete the claimed invention. In the decision *In re Lundberg*, 117 USPQ 190, 1958, the CCPA held that "advantages which are not disclosed in application cannot be urged as basis for allowing claims"

7) Claims 27 to 119 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

8) Claims 27 to 119 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by the Kitson et al. publication (NATURE 384:372-375, 28 Nov. 1996) for those reasons of record in section 8 of Paper Number 9.

9) Applicant's arguments filed 21 May of 2001 have been fully considered but they are not persuasive for those reasons given above.

10) All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first

action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JOHN ULM
PRIMARY EXAMINER
GROUP 1800